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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,658	03/20/2001	Chieko Kitada	2549US0P	4776

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EXAMINER	
LANDSMAN, ROBERT S	
ART UNIT	**PAPER NUMBER**
1647	11

DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/787,658	Applicant(s) KITADA ET AL.	
	Examiner Robert Landsman	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Formal Matters

A. Amendment A, filed 4/24/03, has been entered into the record.

B. The Information Disclosure Statement, filed 4/24/03, has been entered into the record.

C. Claims 1-28 are pending in this application and are the subject of this Office Action.

D. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Action.

2. Bibliographic Data Sheet

A. The issue regarding foreign application JP 10/271626 was not addressed by Applicants. Therefore, a change to the Bibliographic Data Sheet will be made if this case is allowable, unless Applicants request a corrected Filing Receipt.

3. Title

A. The objection to the title has been withdrawn in view of Applicants' amendment.

4. Specification

A. The objection to the specification has been withdrawn in view of Applicants' amendment to include the priority data in the first line of the specification.

5. Claim Objections

A. The objection to claims 1-28 has been withdrawn in view of Applicants' addition of specific SEQ ID NOs to the claims.

B. Claims 2-28 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As discussed in the below rejection under 35 USC 112, second paragraph, claim 1 recites specific SEQ ID NOs. Claims 2-2.

6. Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

A. Claims 1-28 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific, substantial and credible asserted utility or a well established utility. These claims are directed to peptides which bind to an orphan receptor (APJ). However, the invention encompassed by these claims has no apparent or disclosed patentable utility. This rejection is consistent with the current utility guidelines, published 1/5/01, 66 FR 1092. The instant application has provided a description of an isolated protein (APJ). However, the instant application does not disclose a specific and substantial biological role of this protein or its significance.

It is clear from the instant specification that the claimed receptor is what is termed an "orphan receptor" in the art. The instant application does not disclose the biological role of the claimed protein or its significance. There is little doubt that, after complete characterization, this protein will probably be found to have a patentable utility. This further characterization, however, is part of the act of invention and, until it has been undertaken, Applicants' claimed invention is incomplete.

Applicants have provided post-filing references showing that the APJ receptor binds apelin and is involved in HIV infection. However, this utility was not disclosed in the specification as originally filed. Applicants do mention that the peptides of the invention could be used with relation to AIDS. However, this utility was, respectfully, disclosed among a litany of unrelated diseases. Therefore, the instant claims are drawn to peptides to a protein which had, as of the filing date, a yet undetermined function or biological significance. There is no actual and specific significance which can be attributed to said protein identified in the specification. For this reason, the instant invention is incomplete. In the absence of a knowledge of the natural ligands or biological significance of this protein, there is no immediately obvious patentable use for it. To employ a protein of the instant invention in the identification of substances which bind to and/or mediate activity of the said receptor is clearly to use it as the object of further research which has been determined by the courts to be a non-patentable utility. Since the instant specification does not disclose a "real-world" use for said protein then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. 101 as being useful.

Furthermore, since the protein of the invention are not supported by a specific and substantial asserted utility or a well established utility, the peptides which bind to this receptor also lack utility.

7. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to use the instant invention. Specifically, since the claimed invention is not supported by a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

B. Claims 26-28 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on page 3 of the Office Action dated 11/28/03. Applicants argue that the scope of claim 1 has been limited to specific sequences and that claim 26 recites pharmaceutical compositions. However, this argument is not deemed persuasive. Thought Applicants have limited the claims to specific SEQ ID NOs, the breadth is still excessive with regard to Applicants claiming pharmaceutical compositions to treat any and all diseases. Applicants have provided no guidance or working examples of what diseases can be treated with the peptides of the present invention, or more importantly, how to use the peptides to treat any disease. Again, Applicants provide a litany of unrelated disease with no guidance how to treat any disease, nor would it be predictable to the artisan how to treat any disease using these peptides, especially given that the utility of the APJ receptor was not known at the time of filing.

Therefore, in summary, the breadth of the claims remains excessive with regard to Applicants claiming pharmaceutical compositions to treat any and all diseases. Applicants have provided no guidance or working examples of how to use the peptides to treat any disease, nor would it be predictable to the artisan how to treat any disease using these peptides. For these reasons, the Examiner maintains that undue experimentation would be required to practice the invention as claimed.

8. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 26-28 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on page 4 of the Office Action dated 4/24/03. Applicants argue that the scope of claim 1 has been limited to specific sequences and that claim 26 recites pharmaceutical compositions. However, this argument is not deemed persuasive. Thought Applicants have limited the claims to specific SEQ ID NOs, they still have not adequately described what diseases can be treated, nor have they described how to treat the host of diseases disclosed in the specification. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe how to use the peptides of the invention, one of skill in the art would

reasonable conclude that the Applicant was not in possession of the claimed genus at the time the invention was made.

9. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are confusing since claim 1 has been amended to limit the claims to specific SEQ ID NO:s, as suggested by the Examiner. However, claim 1, in addition to reciting the specific SEQ ID NOs, also recites a general formula and desired substitutions in the claim. This is confusing since the recited SEQ ID NOs already exactly define the peptide. Therefore, no recitation of a peptide with variables would be required. Similarly, the dependent claims also recite substitutions in the formula of SEQ ID NO:1. Again, however, these claims are requiring substitution of specific variables, which have already been specifically identified by the recited SEQ ID NOs, the claims are confusing. Claim 28 is also confusing since it recites SEQ ID NO:26, which was not one of the elected SEQ ID NOs.

10. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
July 02, 2003

ROBERT LANDSMAN
PATENT EXAMINER